UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

LEDA HEALTH CORPORATION, Plaintiff, v. JAY ROBERT INSLEE et al., Defendant.	CASE NO. 2:24-cv-00871-DGE ORDER ON MOTION FOR INJUNCTION PENDING APPEAL (DKT. NO. 46)

I INTRODUCTION

This matter comes before the Court on Plaintiff Leda Health Corporation's motion for injunction pending appeal. (Dkt. No. 46.) Defendant filed a response (Dkt. No. 51), to which Plaintiff replied (Dkt. No. 52). For the foregoing reasons, the Court DENIES Plaintiff's motion.

II BACKGROUND

On October 21, 2024, the Court denied Plaintiff's motion for a preliminary injunction and granted Defendant's motion to dismiss. (Dkt. No. 42.) The factual and procedural background

of this matter is set forth in detail in the Court's recent order. (*See id.*) Accordingly, only a brief account of the relevant facts is provided herein.

Leda Health is a company known for developing Early Evidence Kits ("EEKs")—products that allegedly enable sexual assault survivors to "self-collect and store evidence such as DNA" if they are unable or unwilling to seek a traditional forensic medical examination. (Dkt. No. 11 at 4.) On October 31, 2022, the Washington State Attorney General's Office (AGO) issued Leda a notification directing the company to "immediately cease and desist from advertising, marketing, and sales to Washington consumers related to its 'Early Evidence Kits' on the basis that Leda's business practices related to these kits violated the Washington Consumer Protection Act." (Dkt. No 19-1 at 29.) The letter stated that "Leda's claims regarding the admissibility of its at-home kits have the capacity to deceive a Washington consumer into believing that its Early Evidence Kits have equivalent evidentiary value to a sexual assault evidence kit ("SAEK") administered by a medical professional." (*Id.* at 30). The notice went on to assert that the self-administered nature of Leda's EEKs would predictably result in "numerous barriers to admission as evidence, including on the basis of potential cross-contamination, spoilation, and validity." (*Id.*) It emphasized that, in Washington, exams by a trained Sexual Assault Nurse Examiner (SANE) are "both free and routinely admissible." (*Id.* at 31.) Thus, the letter concluded that "Leda charging consumers for Early Evidence Kits despite the fact they are unlikely to be admissible in a criminal court is an unfair and deceptive business practice" in violation of the Washington Consumer Protection Act. (*Id.*)

Subsequently, Washington's legislature passed House Bill 1564, "An Act Relating to prohibiting the sale of over-the-counter sexual assault kits." (Dkt. No. 19-1 at 3.) The law went into effect on July 23, 2023. (Dkt. No. 30 at 13.) Several representatives from Leda Health

testified at hearings on the bill, asserting that Leda's kits are not misleading but rather intended to be an additive option for the approximately 70% of sexual assault victims who do not go to the hospital, or for those who go but are not able to see a SANE nurse. (Dkt. No. 13 at 181.) Leda further stated that while the company did not guarantee evidence admissibility, it had procedures in place to establish chain of custody and believed that evidence from its kits should be admissible in court. (*Id*.) Thus, it concluded "[t]he sale of over-the-counter sexual assault kits may prevent survivors from receiving accurate information about their options and reporting processes; from obtaining access to appropriate and timely medical treatment and follow up; and from connecting to their community and other vital resources." *Id*.

Entitled "[o]ver-the-counter sexual assault kits" and codified at Washington Revised Code § 5.70.070, the act establishes that:

> (2) A person may not sell, offer for sale, or otherwise make available a sexual assault kit:
>
> a) That is marketed or otherwise presented as over-the-counter, at-home, or self-collected or in any manner that indicates that the sexual assault kit may be used for the collection of evidence of sexual assault other than by law enforcement or a health care provider; or
>
> b) If the person intends, knows, or reasonably should know that the sexual assault kit will be used for the collection of evidence of sexual assault other than by law enforcement or a health care provider.

Wash. Rev. Code § 5.70.070(2). The statute defines "sexual assault kit" as "a product with which evidence of sexual assault is collected." Wash. Rev. Code § 5.70.070(1). It further stipulates that a violation of the section constitutes "an unfair or deceptive act in trade or commerce and an unfair method of competition for the purpose of applying [Washington's] consumer protection act." Wash. Rev. Code § 5.70.070(3).

On June 17, 2024, Plaintiff filed a Complaint for declaratory and injunctive relief, asserting that Washington Revised Code § 5.70.070 (hereinafter "the Statute") was

unconstitutional on multiple counts in violation of 42 U.S.C. § 1983. (Dkt. No. 1.) The Complaint claimed that the Statute impermissibly regulated protected speech in violation of the First and Fourteenth Amendments and was thus unconstitutional facially and as applied to Leda Health. (*Id*. at 13–16.) The complaint further alleged that the Statute was void for overbreadth and vagueness, both facially and as applied, and that it constituted an unconstitutional bill of attainder. (*Id*. at 16–20.) Plaintiff moved for a preliminary injunction to prevent enforcement of the Statute (Dkt. No. 10) and Defendant filed a motion to dismiss (Dkt. No. 30). The Court found that the merits of Plaintiff's claims failed as a matter of law; accordingly, the Court denied Plaintiff's motion for a preliminary injunction and granted Defendant's motion to dismiss. (Dkt. No. 42.)

Plaintiff subsequently filed the instant motion for injunction pending appeal, arguing that the "[t]he Court erred" in finding that Leda failed to put forth a cognizable facial First Amendment claim. (Dkt. No. 46 at 3.) Because the Statute violates Leda's First Amendment rights, Leda asserts, the company is entitled to an injunction pending appeal. (*Id*.) Leda does not address the other constitutional arguments it raised in its original motion for preliminary injunction—thus, the motion at hand is based entirely upon its facial First Amendment challenge to the Statute. (*Id*.) Defendant argues that "Leda presents no new arguments justifying an injunction pending appeal" and thus "Leda is still not likely to succeed on the merits of its free speech claims." (Dkt. No. 51 at 5.)

III LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 62(d), the Court may grant an injunction on terms . . . that secure the opposing party's rights" pending appeal of "an interlocutory order or final judgment that grants, continues, modifies, refuses, dissolves, or refuses to dissolve or

modify an injunction." "The standard for evaluating an injunction pending appeal is similar to that employed . . . in deciding whether to grant a preliminary injunction." *Feldman v. Ariz. Sec. of State's Office*, 843 F.3d 366, 367 (9th Cir. 2016). Thus, "[i]n evaluating a motion for an injunction pending appeal, [courts] consider whether the moving party has demonstrated [1] that they are likely to succeed on the merits, [2] that they are likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in their favor, and [4] that an injunction is in the public interest." *South Bay United Pentecostal Church v. Newsom*, 959 F.3d 938, 939 (9th Cir. 2020). The Ninth Circuit also permits an alternative test in which "'serious questions going to the merits and a hardship balance that tips sharply toward the plaintiff can support issuance of an injunction, assuming the other two elements are also met." *All. for the Wild Rockies v. Cottrell*, 532 F.3d 1127, 1132 (9th Cir. 2011).

IV DISCUSSION

A. Likelihood of Success or Serious Questions

In its prior order denying Plaintiff's motion for a preliminary injunction, the Court found the Statute is an economic regulation of the sale of a product and not a regulation of speech. (Dkt. No. 42 at 12.) To the extent the Statute incidentally implicates speech, the Court concluded it is commercial in nature. (*Id*.) The Supreme Court has developed a four-part test for evaluating the permissible regulation of commercial speech. *Central Hudson Gas & Electric Corp. v. Public Service Commission* 447 U.S. 557, 566 (1980). "At the outset" a court must determine whether the expression is protected at all; "[f]or commercial speech to come within that provision, it at least must concern lawful activity and not be misleading." *Id*. The Court determined the commercial speech at issue relates to illegal activity and is therefore not

protected. (Dkt. No. 42 at 14.) Accordingly, the Court did not move past the first *Central Hudson* step.

In its motion for injunction pending appeal, Leda asserts the statute implicates protected speech and suggests "the Court did not conduct the actual speech analysis" under *Central Hudson*. (Dkt. No. 46 at 7.) At a minimum, Leda argues, its motion "raise[s] serious questions going to the merits." (*Id*.) (citing *Al. for the Wild Rockies*, 632 F.3d at 1135). The Court cannot find serious questions going to the merits of the First Amendment question for two reasons, however. First, the Court is not persuaded that its First Amendment analysis was "wrong"; it once more finds the Statute is an economic regulation of a product and not a speech regulation. (Dkt. No. 46 at 6.) Second, even if the Statute *is* construed as regulating legal, non-misleading commercial speech, the legislation satisfies the *Central Hudson* factors and therefore passes constitutional muster on separate grounds.

1. Speech as Presumptive Evidence of Product Type Does Not Implicate the First Amendment

Leda argues the Court erred in finding the statute does not implicate protected speech. (Dkt. No. 46 at 2.) In construing the Statute, the Court determined it closely resembles the statutory regimes at issue in two D.C. Circuit cases—*Nicopure Labs, LLC v. Food & Drug Admin* and *Whitaker v. Thompson*. *See* 944 F.3d 267, 282 (D.C. Cir. 2019); 353 F.3d 947, 953 (D.C. Cir. 2004)). Both *Whitaker* and *Nicopure* involved FDA regulations that "use [] a product's marketing and labeling to discern to which regulatory regime a product is subject, and [] treat [the product] as unlawful insofar as it is marketed under a different guise." *Nicopure*, 944 F.3d at 282. The D.C. Circuit held "the FDA d[oes] not run afoul of the First Amendment when it relies on manufacturer statements" in this way. *Id*. The *Whitaker* panel grounded this

holding in the principle that "the use of speech to infer intent, which in turn renders an otherwise permissible act unlawful, is constitutionally valid." *Whitaker*, 353 F.3d at 953.

Leda argues that *Nicopure* and *Whitaker* are "not analogous" and that there is, in fact, "no . . . example of similar valid statute—where the 'stated use' in the marketing of a legal item turns it from legal to illegal to sell." (Dkt. No. 46 at 5.) Not so. In *Nicopure*, the regulation at issue established: "No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product," unless the product is cleared by the FDA. *Nicopure* 944 F.3d at 277 (citing 21 U.S.C. § 387k). The regulation *defines* "modified risk tobacco product" as a product "the label, labeling, or advertising of which represents explicitly or implicitly that [] the tobacco product presents a lower risk of tobacco-related disease… [or] the label, labeling or advertising of which uses the descriptors 'light,' 'mild' or 'low'[.]" *Id*. Thus, "[w]hether a product falls in the modified risk category turns on how the manufacturer describes the product's characteristics and intended use." *Id*. at 283. In this way, "selling an e-cigarette as less risky . . . renders the sale-as-labeled unlawful." *Id*. Despite Leda's strained characterization to the contrary, "the 'stated use' in the marketing" does indeed determine whether one may legally sell the tobacco product.

Likewise, *Whitaker* involved a statutory regime in which the "classification of a substance as a 'drug' turn[ed] on the nature of the claims advanced on its behalf." *Whitaker*, 353 F.3d at 953. As the *Nicopure* court stated, "[i]n *Whitaker* . . . . [o]nce the manufacturer made a 'drug claim' regarding treatment of a disease or its symptoms, it was required to clear the FDA's drug approval pathway, and its sale accompanied by a drug claim without approval as a drug became unlawful." *Nicopure* 944 F.3d at 283. Just as it is illegal for manufacturers to sell "saw palmetto" (the substance at issue in *Whitaker*) under a label describing its effectiveness in

treating prostatic hyperplasia, Leda and other manufacturers cannot sell a "kit" that is labeled for self-collection of sexual assault evidence. *See Whitaker*, 353 F.3d. at 233.

As the Court was not provided with any analogous caselaw to the contrary, it applied the D.C. Circuit's well-reasoned conclusion that the use of a claim made by the manufacturer to determine whether a product is subject to regulation does not constitute a regulation of speech. (Dkt. No. 42 at 9–11.) The Court's holding was further supported by similar First Circuit precedent. *See Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71 (1st Cir. 2013) (description on label as presumptive evidence of product classification for the purposes of banning the product's sale does not implicate speech). Moreover, the First, Second, and Seventh Circuits have uniformly concluded that the evidentiary use of promotional speech to establish a product's intended use—and thereby determine whether it is a mislabeled "drug" under the FDCA—does not implicate the First Amendment. *See United States v. LeBeau*, 654 F. App'x 826, 830–831 (7th Cir. 2016) (explaining that the prosecutor's use of the Defendant's statements to determine how he intended consumers to use his product, and therefore to determine whether the product qualified "as a drug," did not constitute prosecution "for having made claims about his products" but rather prosecution for "*acts*—his attempt to profit from the sale of a product—which he represented to have palliative properties—without having received approval") (emphasis in original); *United States v. Facteau*, 89 F.4th 1, 25 (1st Cir. 2023), cert. denied, No. 23-1016, 2024 WL 4426540 (U.S. Oct. 7, 2024) (collecting cases). This caselaw is persuasive, as the Statute prohibits the sale of sexual assault kits based on the kit's intended use—at-home evidence collection—which may be determined by claims from the manufacturer that the kits are *for* at-home evidence collection. Finally, the operative verbs of the Statute—"sell," "offer for sale," and "make available"—further support the construction of the Statute as

an economic regulation of a particular product, as they contemplate transactional conduct and not speech or expression. *C.f. Williams*, 533 U.S. at 294.

As Leda has failed to direct the Court to any additional caselaw, the Court once more finds that the statute does not implicate protected speech.

2. Permissible Regulation of Commercial Speech

As the Ninth Circuit noted in *Sammartano v. First Judicial Court*, "the fact that a case raises serious First Amendment questions compels a finding that there exists the potential for irreparable injury." 303 F.3d 959, 973 (9th Cir. 2002) (*abrogated on other grounds by Winter*, 555 U.S. 7). Leda asserts that, at minimum, it has "raised serious questions going to the merits" and that it therefore also meets the balance of hardships factor. (Dkt. No. 46 at 7) (citing *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011)). However, the Court cannot find that this matter raises "significant" First Amendment questions because *even if* the Statute is taken as a regulation of speech, the legislation satisfies the *Central Hudson* factors and therefore passes constitutional muster. *See Central Hudson*,447 U.S. at 566.

In its prior order, the Court determined that—to the extent the Statue implicates speech—the speech in question is commercial in nature. (Dkt. No. 42 at 12–13).[1] However, the Court did

[1] "Speech [can] properly be characterized as commercial when (1) the speech is admittedly advertising, (2) the speech references a specific product, and (3) the speaker has an economic motive for engaging in the speech." *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1106 (9th Cir. 2004) (citing *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66–67 (1983)). The Ninth Circuit has declined to limit the scope of commercial speech to "circumstances where clients pay for services," emphasizing that advertisements or marketing that is "placed in a commercial context and directed at the providing of services rather than toward an exchange of ideas" qualifies as commercial speech even if the solicitation is of a non-paying client base. *First Resort, Inc. v. Herrera*, 860 F.3d 1263, 1273 (9th Cir. 2017). The Statute prohibits "offering" sexual assault kits "for sale"— speech that "does no more than propose a commercial transaction." *Bolger*, 463 U.S. at 66. Even a hypothetical "offer for sale" at no cost (free distribution of EEKs) would still explicitly "reference the product" itself and be directed at the

not conduct the full, four-part *Central Hudson* analysis, as it found that any offer for sale of an EEK constitutes an offer to engage in an illegal transaction, and such speech is "categorically excluded from First Amendment protection." *Williams*, 553 U.S. at 297; *Levi Strauss & Co. v. Shilon*, 121 F.3d 1309, 1312 (9th Cir. 1997); *see also Nicopure*, 944 F.3d at 284 (citing *Hoffman Estates*, 455 U.S. at 496) ("speech proposing an illegal transaction is speech which a government may regulate or ban entirely . . . the FDA does not run afoul of the First Amendment when it relies on manufacturer statements"). Likewise, any marketing represents "commercial speech related to illegal activity" if Leda attempts to sell kits with the intent that they be used for at-home evidence collection. *Central Hudson*, 447 U.S. at 564. Thus, it is not necessary to move past this initial *Central Hudson* step.

Assuming arguendo the speech concerns lawful activity, the Court must then determine it is not misleading, as misleading speech is likewise unprotected. *See Central Hudson*, 447 U.S. at 566 ("At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading."). The Washington Legislature concluded "[a]t-home sexual assault test kits create false expectations" (2023 Wash. Sess. Laws, ch. 296, § 1) and the Attorney General found Leda's claims about the admissibility of the evidence had the capacity to deceive consumers. (Dkt. No 19-1 at 29.) Accordingly, there is—at minimum—a serious

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"provision of services"—services that are typically provided so that the company can turn a profit. *Joseph*, 353 F.3d at 1006; *Herrera*, 860 F.3d, at 1263. This too meets the definition of commercial speech. To the extent that the marketing language in subsection 2(a) burdens speech, it only does so if a person is selling a kit that is "marketed or otherwise presented as over-the-counter"; critically, it is the sale or distribution of a product meeting the description in 2(a) that triggers the statute. Thus, to the extent that the Statute implicates speech, the speech is "'linked inextricably' with the commercial arrangement that it proposes." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) (quoting *Friedman v. Rogers*, 440 U.S. 1, 10, n. 9 (1979)).

question about whether Leda's speech is misleading, especially because "[t]he First Amendment test of regulation of potentially misleading commercial speech allows for contextual determination of accuracy based on consumers' understanding." *Nicopure*, 944 F.3d at 287; *see also In re R. M. J.*, 455 U.S. 191, 200 (1982) (when "the public lacks sophistication," certain statements may be found misleading that would otherwise be considered unimportant). In certain circumstances, an "overall net impression" received by a "significant minority of reasonable consumers" can indicate that speech is misleading. *Nicopure*, 944 F.3d at 287 (quoting *POM Wonderful, LLC v. FTC.*, 777 F.3d 478, 490 (D.C. Cir. 2015)). Thus, the speech in question may well fail this initial *Central Hudson* step as well. However, for the purposes of the current order, the Court does not reach this question.

Assuming the speech concerns lawful activity and is not misleading, step two of the *Central Hudson* test looks to "whether the asserted government interest is substantial." *See Central Hudson*, 447 U.S. at 566. If it is, the Court must find that the regulation directly advances the governmental interest asserted and that it is not more extensive than necessary to serve that interest. *Id.* Neither Plaintiff nor Defendant denies that Washington's stated interest in "support[ing] survivors of sexual offenses through . . . systems that promote successful investigations and prosecutions of sexual offenses," including by "preserve[ing] [] forensic evidence" and ensuring that survivors receive accurate information and timely medical attention is substantial. 2023 Wash. Sess. Laws, ch. 296, § 1. Indeed, many Courts have affirmed the state's substantial interest in protecting victims, including through securing needed evidence. *See, e.g., In re Grand Jury Empaneling of Special Grand Jury*, 171 F.3d 826, 832 (3d Cir. 1999) (finding the state has a compelling interest in securing evidence to punish criminal activity); *United States v. Morrison*, 529 U.S. 598, 599 (2000) ("[T]here is no better example of the police

power, which the Founders undeniably left reposed in the States . . . than the suppression of violent crime and vindication of its victims."). This factor is therefore established.

Next, the Court must determine that the government's regulation directly advances the substantial interest; "the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose." *Central Hudson*, 447 U.S. at 564. Here, the regulation directly addresses the issues the government identified. By banning the sale and distribution of sexual assault kits marketed for at-home use, the Statute dramatically reduces the odds that survivors will access at-home kits that may later be found inadmissible in court, otherwise hamper prosecution efforts, or serve as an inadequate stand-in for timely medical examination following an assault.

Step four "complements" step three by "asking whether the speech restriction is not more extensive than necessary to serve the interests that support it." *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 188 (1999). "[T]he least restrictive means is not the standard; instead, the case law requires a reasonable fit between the legislature's ends and the means chosen to accomplish those ends, a means narrowly tailored to achieve the desired objective." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 556 (2001) (cleaned up); *see also Bd. of Trustees of State Univ. of New York v. Fox*, 492 U.S. 469, 480 (1989) ("What our decisions require is a 'fit' between the legislature's ends and the means chosen to accomplish those ends, a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served[.]") (internal quotations removed.). It is generally "up to the legislature to choose between narrowly tailored means of regulating commercial speech." *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1111 (9th

Cir. 2004). Courts are "loath to second-guess the Government's judgment to that effect." *Fox*, 492 U.S. at 478 (1989) (collecting cases).

The Statute "is a reasonable fit between the legislature's ends and the means chosen to accomplish those ends." *Joseph*, 353 F.3d at 1111. In this case, the central issue the legislature sought to address stemmed from the very *existence* of the product in the stream of commerce. *See* 2023 Wash. Sess. Laws, ch. 296, § 1. ("[A]t-home sexual assault test kits create false expectations and harm the potential for successful investigations and prosecutions."). Accordingly, the scope of the law (a ban on the sale of sexual assault kits marketed for at home use) is sufficiently tailored to the end of preventing the use of such kits. It is not for the Court to second guess the legislature's identification of the *problem* itself—a matter that involved days of hearings and fact finding. *See Pearson v. Edgar*, 153 F.3d 397, 404 (7th Cir. 1998) ("We declined to second-guess the Illinois General Assembly's judgment that real estate solicitation poses a special problem to residential privacy because even on matters touching the First Amendment, courts must accept plausible judgments by other governmental actors.") (cleaned up); *Clear Channel Outdoor, Inc. v. City of New York*, 594 F.3d 94, 105 (2d Cir. 2010). The legislature's policy judgment to prohibit the sale of a product it deemed harmful is not only reasonable but also a typical regulatory move. *See LC&S, Inc. v. Warren Cnty. Area Plan Comm'n*, 244 F.3d 601, 604 (7th Cir. 2001) ("It is utterly commonplace for legislation to be incited by concern over one person or organization.").

In sum, even if the Statute is treated as a speech regulation implicating the First Amendment, it meets the *Central Hudson* standard. Thus, Leda's claim fails as a matter of law for two separate reasons and does not represent a serious question going to the merits.

B. Remaining Factors

Plaintiff has failed to establish a likelihood of success on or serious questions going to the merits. If the plaintiff fails to "establish[ ] serious questions going to the merits . . . [courts] need not consider the remaining factors for an injunction." *Doe v. San Diego Unified Sch. Dist.*, 19 F.4th 1173, 1181 (9th Cir. 2021). Without a "threshold showing" of a likelihood of success on the merits, the Court cannot grant Plaintiff's motion for injunction pending appeal. *E. Bay Sanctuary Covenant v. Garland*, 994 F.3d 962, 975 (9th Cir. 2020) (quoting *Leiva-Perez v. Holder*, 640 F.3d 962, 966 (9th Cir. 2011)). Thus, because Plaintiff has failed to demonstrate that the first factor weights in its favor, the Court's inquiry is at an end.

V CONCLUSION

Accordingly, Plaintiff's motion for injunction pending appeal (Dkt. No. 46) is DENIED.

Dated this 3rd day of January, 2025.

David G. Estudillo
United States District Judge